

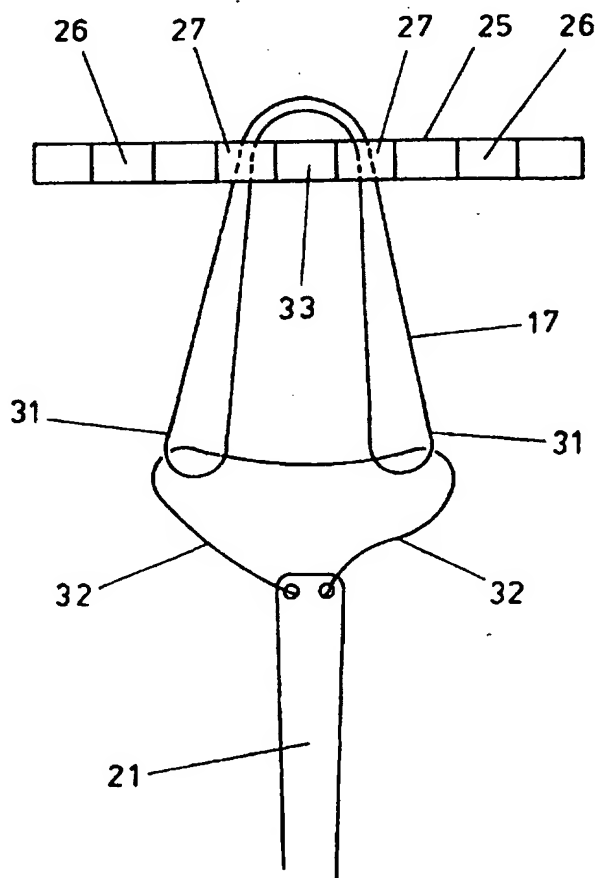
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/GB97/02613 (22) International Filing Date: 26 September 1997 (26.09.97) (30) Priority Data: 9620046.4 26 September 1996 (26.09.96) GB (71) Applicant: NEOLIGAMENTS LIMITED [GB/GB]; 28-30 Blenheim Terrace, Leeds LS2 9HD (GB). (72) Inventors: SEEDHOM, Bahaa, Botros; Neoligaments Limited, 28-30 Blenheim Terrace, Leeds LS2 9HD (US). OCHI, Mitsuo; Shimane Medical University, Dept. of Orthopaedic Surgery, 89-1, Enya-cho, Izumo, Shimane 693 (JP). (74) Agent: ORR, William, McLean; Urquhart-Dykes & Lord, Tower House, Merrion Way, Leeds LS2 8PA (GB).</p>		<p>(81) Designated State: JP. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: METHOD OF ASSEMBLY OF ATTACHMENT DEVICE FOR LIGAMENT IMPLANTATION

(57) Abstract

A method of assembly of an attachment device for use in guiding a prosthetic ligament (21) to a required position in a bone tunnel formed in a bone joint (10) between two adjacent bones (11, 12), and to anchor one end of the ligament, said device comprising: an elongate guide element (16) which is manipulatable between a pulling position in which its longitudinal axis extends generally parallel to the pulling direction and an anchoring position in which its longitudinal axis extends transversely of the pulling direction; connecting means (26) provided on the guide element (16) to permit pulling means (22) to be connected to the element in order to pull the guide element, and a trailing implantation system connected thereto, through the bone tunnels with the guide element orientated so that its longitudinal axis extends generally parallel to the pulling direction until the element emerges from the mouth (33) at one end of one of the tunnels, whereby the guide element is manipulatable by the pulling means so as to overlie the mouth and thereby anchor one end of the implantation system; a connecting loop (17) for connection to the guide element (25); connecting apertures (27) formed in the guide element (16) to permit the loop (27) to be connected thereto; in which the loop (27) is made of flexible and implantable material comprising a cohesive assembly of twisted filaments, and is connected to the apertures (27) in the guide element (16) by feeding the loop through the apertures (27) so as to make a U-shaped form with free ends (31) to which the ligament (21) can be connected.



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METHOD OF ASSEMBLY OF ATTACHMENT DEVICE
FOR LIGAMENT IMPLANTATION

This invention is concerned generally with the implantation of a prosthetic ligament, and in particular with providing a method of assembly of an attachment device for use in guiding a prosthetic ligament to a required position within a bone joint, and to anchor one end of the ligament.

In the implantation of a prosthetic ligament in a bone joint e.g. the knee joint between tibial and femoral components, it is usual to drill tunnels through the bones, and to pull the prosthetic ligament through the tunnels until a required position is reached within the joint, followed by suitable anchoring of the ligament against linear movement in either direction. The anchoring may involve use of bone staples or other intrusive fixations, which attach tensile elements (connected to each end of the ligament) to suitable bone sites adjacent to the mouths of the bone tunnels.

Prosthetic ligaments can be made of synthetic material, provided that it is of suitable implantable nature, and which may be woven, or autogenous tissue harvested from the patient can be used.

One more recent endoscopic technique which has been developed in ACL reconstruction (anterior cruciate ligament reconstruction), involves use of an attachment device which serves both to guide the implantation of the ligament, and to secure one end of the ligament against axial movement in one direction, but the attachment device is of such a construction that it does not need to anchor itself in position by physical intrusion into the bone.

The attachment device used in the technique provides easy guidance of the ligament, by forming the lead element of a trailing implantation system, and which passes through the usual drilled-out bone tunnels, and then upon exiting of the lead element from an upper mouth of one of the tunnels i.e. when it projects upwardly out of the femoral component, a simple manipulation of the device causes it to overlie the mouth of the tunnel, and thereby provide tensile restraint for the ligament end of the now implanted ligament to which it is

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attached.

The attachment device therefore is capable of being manipulated between a pulling position, in which it has reduced lateral extent relative to the pulling direction, and to an anchoring position in which it has maximum lateral extent relative to the pulling direction.

This known attachment device comprises a small metal bar which is about 12mm in length, 4mm wide and 1.5mm in thickness, and has a row of four circular holes extending through it, of which the two outermost holes serve for attachment of two separate pulling sutures, and the inner pair of holes serve to attach the metal bar to the trailing ligament via a further set of sutures. The set of pulling sutures is taken first through the lower end of the lowermost bone tunnel in the tibial component and then passes upwardly through the bone tunnel in the femoral component, and pulls the trailing ligament system behind it. In practice only one of the sutures has tension applied to it sufficient to pull the metal bar behind it with the bar manipulating itself to take-up the pulling position of reduced lateral projection, and to be pulled lengthwise through the tunnels. Since the bar orientates itself so that its longitudinal axis aligns itself with the pulling direction, the diameter of the final passage drilled through the femoral component can be reduced, compared with the larger diameter of the tunnel which is formed so as to receive the implanted ligament. This final passage therefore can have a diameter of slightly more only than the maximum transverse dimension of the bar (4mm). Upon exiting from the femoral component, the other pulling suture is then operated so as to manipulate the bar to take-up a transverse position in which its longitudinal axis is generally perpendicular to the passage whereby it can overlie the exit mouth of the small diameter passage. Downward tension applied to the trailing assembly attached to the bar then anchors the attachment bar in position in a non-intrusive manner with respect to the surrounding bone.

The trailing assembly which follows the pulling-through of the attachment bar usually comprises (a) further sutures

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which are taken through the central pair of holes in the bar, and then connected together to complete the formation of a loop by knotting together of the ends of the sutures, and (b) the prosthetic ligament which is attached to the looped sutures in any convenient manner.

In the case of harvested tissue which comprises tendon material and boney material (plugs) attached at each end of the tendon material, the sutures are taken through holes formed in one of the bone plugs and then knotted to complete the formation of the attachment loop.

This known technique and attachment device is recognised as being a useful advance in the art of ligament implantation, and the present invention seeks to further improve this known device and technique, to gain further technical advantages which will facilitate the use by a surgeon in carrying out assembly of an implantation system for a particular patient.

According to the invention there is provided a method as defined in claim 1.

Preferred embodiments of the invention will now be described in detail, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic illustration of the femoral and tibial components of a knee joint, in which ACL reconstruction is to take place;

Figure 2 is a schematic and enlarged view of an implantation system to be made by a method of assembly according to the invention, and in which the system is intended to be pulled through the bone tunnels formed in the knee joint components shown in Figure 1, to implant a prosthetic ligament and anchor it therein;

Figure 3 is a schematic view, showing implantation of a prosthetic ligament;

Figure 4 is a plan view, to considerably reduced scale, of a guide element of the implantation system;

Figure 5 is a side view of a method according to the invention for the assembly of a pre-formed connecting loop to a guide element of an implantation system; and

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Figure 6 is a schematic view, to an enlarged scale, of a pre-formed loop assembly ready to be connected to the guide element shown in Figures 4 and 5.

Referring first to Figure 1 of the drawings, there is shown a typical type of bone joint with which the invention may be used, and which comprises a knee joint 10 which comprises tibial component 11 and femoral component 12. Enlarged bone tunnels 13 and 14 are drilled through the components 11 and 12, and in which a prosthetic ligament is to be implanted, but it will be noted that the bone tunnel 14 merges into a passage 15 of smaller diameter, the purpose of which will be explained in more detail below.

The described embodiment of the invention provides a method of assembly of an attachment device for use in an implantation system which includes a prosthetic ligament, and which serves to guide the ligament to a required position in a bone tunnel formed in a bone joint between two adjacent bones, and also serves to anchor the leading end of the ligament.

An implantation system is shown schematically in Figure 2, and comprises a guide element 16 which is generally elongate, having a major axis and a minor axis, and which is manipulatable between a pulling position in which its longitudinal axis or major axis extends generally parallel to the pulling direction (as shown in Figure 2), and an anchoring position in which its longitudinal axis extends transversely of the pulling direction.

A pre-formed connecting loop 17 is connected at one end 18 to the guide element 16, and is connected at its opposite end 19 to a leading end 20 of a prosthetic ligament designated generally by reference 21. Prosthetic ligament 21 may be a woven synthetic material ligament, or may comprise autogenous tissue harvested from the patient.

The leading portion of the implantation system comprises pulling means 22, connected to the guide element 16, and the trailing end of the system comprises tensile elements 23 connected to the trailing end 24 of the ligament 21.

The implantation system is shown only schematically in

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Figure 2, and the construction, and means of interconnecting the component parts of the system will be described in more detail below and also shown in more detail in Figures 3 to 5 of the drawings.

Figure 3 shows part of the implantation system anchored in position in the femoral component 12, after it has been pulled through passage 15 and bone tunnel 14, by appropriate manipulation of pulling means 22. As shown in Figure 4, the guide element 16 comprises a metal bar or strip 25 having an outermost pair of holes 26, and a central pair of holes 27, and the pulling means 22 are attached to the outermost pair of holes 26, and the pre-formed loop 17 is connected to the central pair of holes 27.

The pulling means 22 is operated to pull the guide element 25 and the trailing implantation system connected thereto, through the bone tunnels 13 and 14, and the guide element orientates itself so that its longitudinal axis extends parallel to the axes of the tunnels 13 and 14 and in the pulling direction, so that it presents minimum lateral projection from this axis. The metal bar forming the guide element typically may have a length of 10mm, a width of 3mm, and a thickness of 1mm. The final passage 15 in the femoral component 12 is therefore slightly larger in diameter than the transverse dimension of the guide element, thereby allowing the pulling means 22 to pull the guide element 16 (bar 25) through bone tunnel 14 and narrow passage 15, and then emerging from the mouth 33. Figure 3 shows the bar 25, after it has been manipulated to a transversely extending position in which it overlies the mouth 33, and thereby provides anchorage for the leading end 20 of the ligament 21.

The pulling means 22 comprises a pair of pulling sutures, and conveniently each suture is connected to a respective hole 26, and these are pulled through the bone tunnels, and then one of these is used as the main pulling suture to pull the implantation system behind it until such time as the bar 25 emerges from the mouth 33. The other pulling suture can then be pulled in order to manipulate the bar 25 to take-up the

anchoring position.

Referring now to Figure 6, this shows how the pre-formed loop 17 can be formed, prior to being connected to the central pair of holes 27 of the bar 25. The loop 17 is formed from a single yarn, and in which the yarn itself is formed from monofilaments lightly twisted together to give some degree of cohesion, and typically the yarn is formed from, say, ninety-six separate filaments.

The single yarn is then formed into an assembly of overlapping looped portions as shown in Figure 6, and if desired, the looped portions may be lightly twisted together also, so as to provide additional cohesion. Alternatively, or in addition, the looped shape can be maintained by use of simple ties 30, which maintain the looped shape, ie having opposed runs 28 and 29, and opposed return ends.

As an alternative to forming a loosely structured bundle as shown in Figure 6, the single yarn may be formed into overlapping looped portions, and with a simultaneous twisting action, so that a cohesive structure is formed, which can maintain its looped shape by frictional engagement between the looped yarn portions. After completion of the formation of the looped bundle, the ends of the single yarn can be tucked into the fibrous structure.

Referring now in particular to Figures 4 and 5, this shows how the looped bundle 17 can readily be manipulated so as to be connected to the bar 25, by taking the looped bundle 17 through the passages 27, in doubled-over manner shown in Figure 5. The free ends 31 of the doubled over loop 17 then serve as means by which the prosthetic ligament 21 can be securely connected thereto, using flexible connections 32.

Then, with attachment of pulling means 22, the implantation system is fully assembled, and is ready to be implanted in the patient.

The mode of assembly of the pre-formed loop 17 to the bar 25, as shown in Figure 5, is a simple operation, which can be carried out in the surgery prior to implantation, or can be prepared in advance, and the surgeon can choose a required

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length of loop 17 to suit a particular patient. Different lengths of loop 17 may be provided, or alternatively one or more single standard lengths may be provided, and the effective length can be changed, by wrapping turns more than once around a central web 33 between the central pair of holes 27.

Thus, having regard to Figure 3, the distance a (the length of narrow passage 15) and the length of bone tunnel 14 (represented by reference b), will vary from patient to patient, and it is desirable that the leading end 20 of the ligament 21 should be located about a minimum of 20mm from the lower end of the tunnel 14, and the effective length of the loop 17 therefore can readily be adjusted accordingly. Manufacture only of a small range of standard loops can take place, and which can be adjusted to suit different patient requirements at the discretion of the surgeon, who can easily adjust the system to suit particular requirements.

The loop 17 shown in Figure 6 is a fibre bundle or hank, comprising, in a typical case, ninety-six monofilaments very loosely twisted together to form the single yarn, ie at about 48 turns per metre, and held together in a loosely structured fibre bundle by ties 30, as described above.

CLAIMS:

1. A method of assembly of an attachment device for use in guiding a prosthetic ligament (21) to a required position in a bone tunnel formed in a bone joint (10) between two adjacent bones (11, 12), and to anchor one end of the ligament, said device comprising:

an elongate guide element (16) which is manipulatable between a pulling position in which its longitudinal axis extends generally parallel to the pulling direction and an anchoring position in which its longitudinal axis extends transversely of the pulling direction;

connecting means (26) provided on the guide element (16) to permit pulling means (22) to be connected to the element in order to pull the guide element, and a trailing implantation system connected thereto, through the bone tunnels with the guide element orientated so that its longitudinal axis extends generally parallel to the pulling direction until the element emerges from the mouth (33) at one end of one of the tunnels, whereby the guide element is manipulatable by the pulling means so as to overlie the mouth and thereby anchor one end of the implantation system;

a connecting loop (17) for connection to the guide element (25);

connecting apertures (27) formed in the guide element (16) to permit the loop (27) to be connected thereto;

in which the loop (27) is made of flexible and implantable material comprising a cohesive assembly of twisted filaments, and is connected to the apertures (27) in the guide element (16) by feeding the loop through the apertures (27) so as to make a U-shaped form with free ends (31) to which the ligament (21) can be connected.

2. A method according to claim 1, in which the loop (17) comprises a single yarn of twisted together monofilaments, and in which the yarn is formed into overlapping looped portions to complete the formation of the loop.

3. A method according to claim 2, in which the overlapping looped portions are held in looped form assembly by

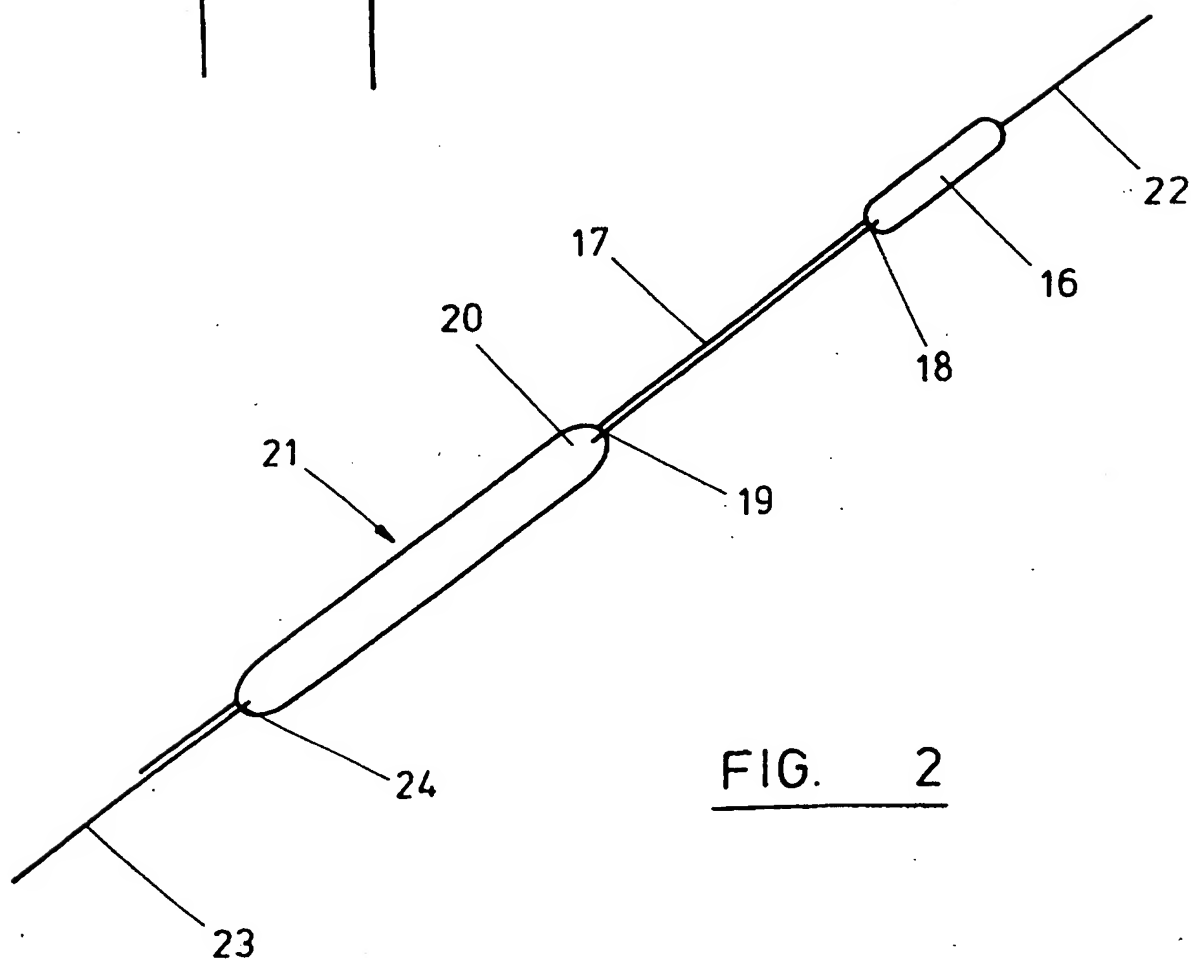
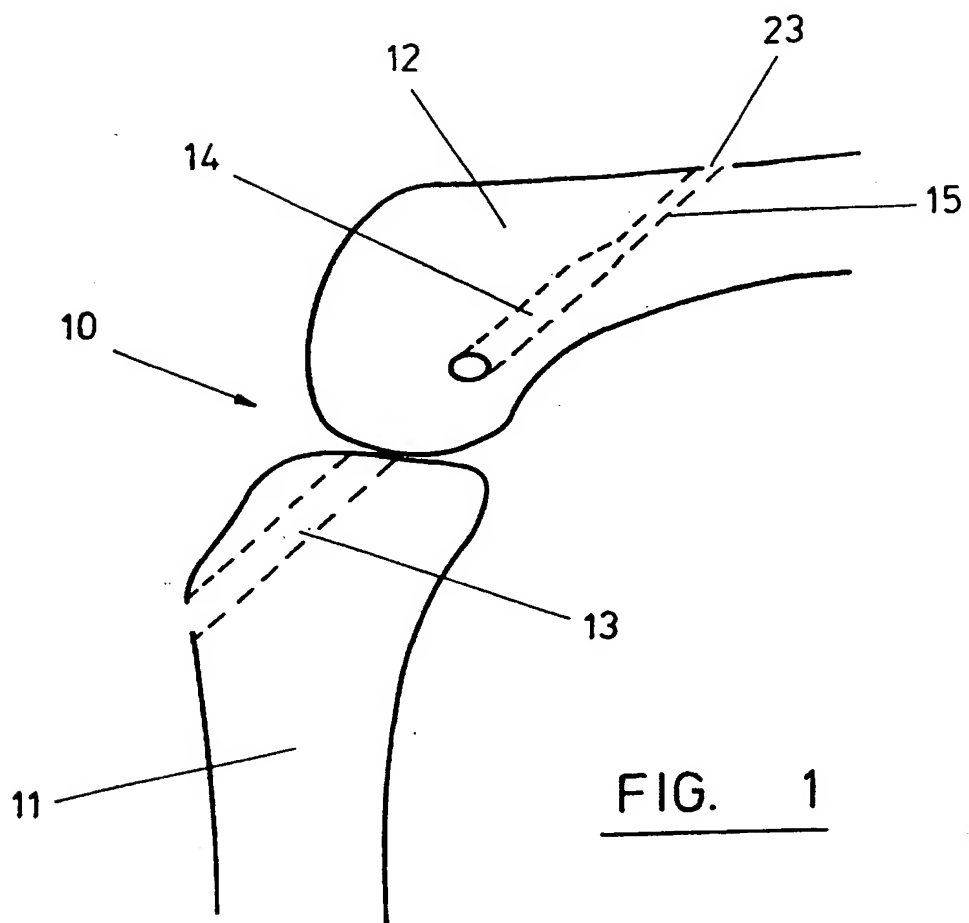
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ties (30).

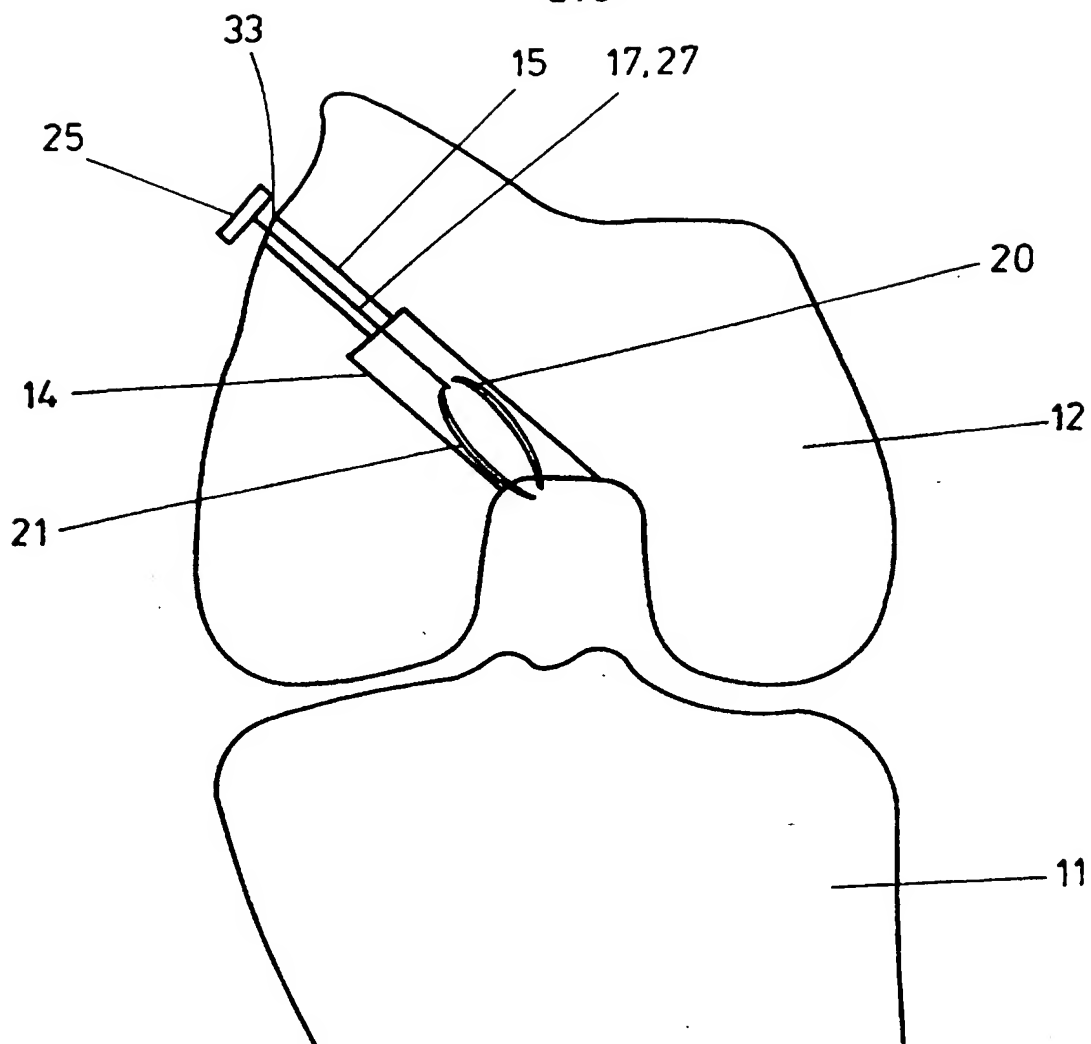
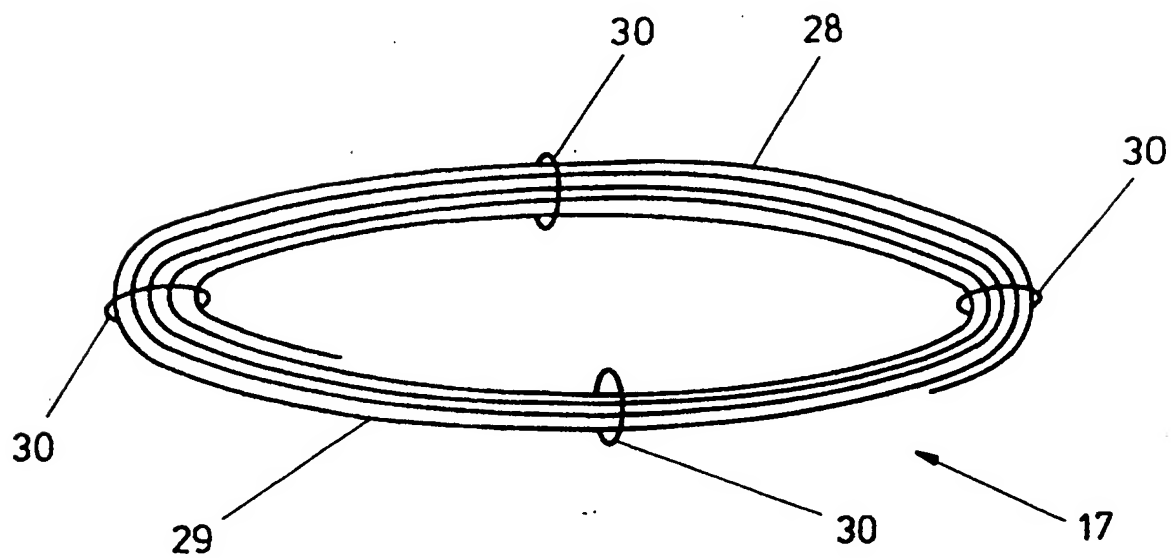
4. A method according to claim 2, in which the overlapping looped portions are twisted together to form a cohesive fibre bundle maintaining its looped shape.

5. A method according to any one of claims 1 to 4, in which the effective length of the loop (17), when connected to the guide element (16), is adjustable by wrapping the loop around a connecting web (33) between the connecting apertures (27).

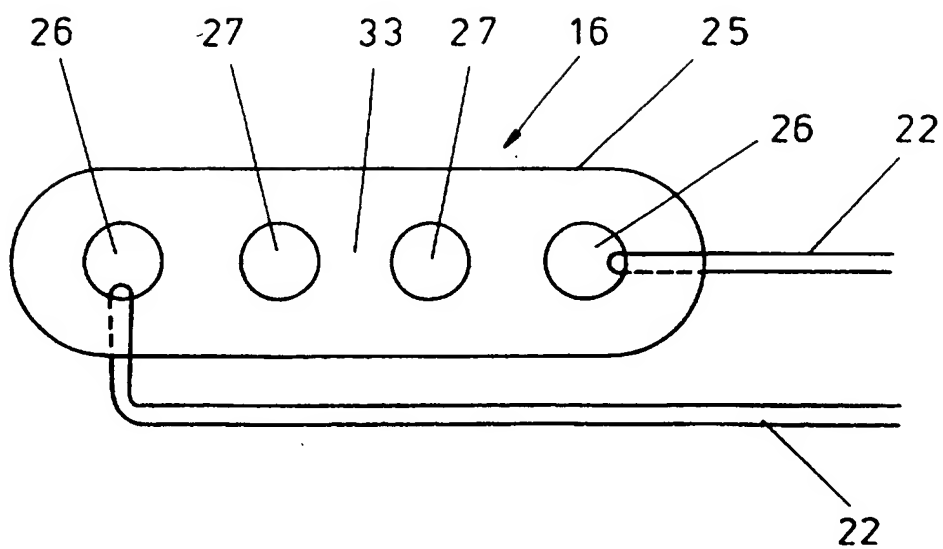
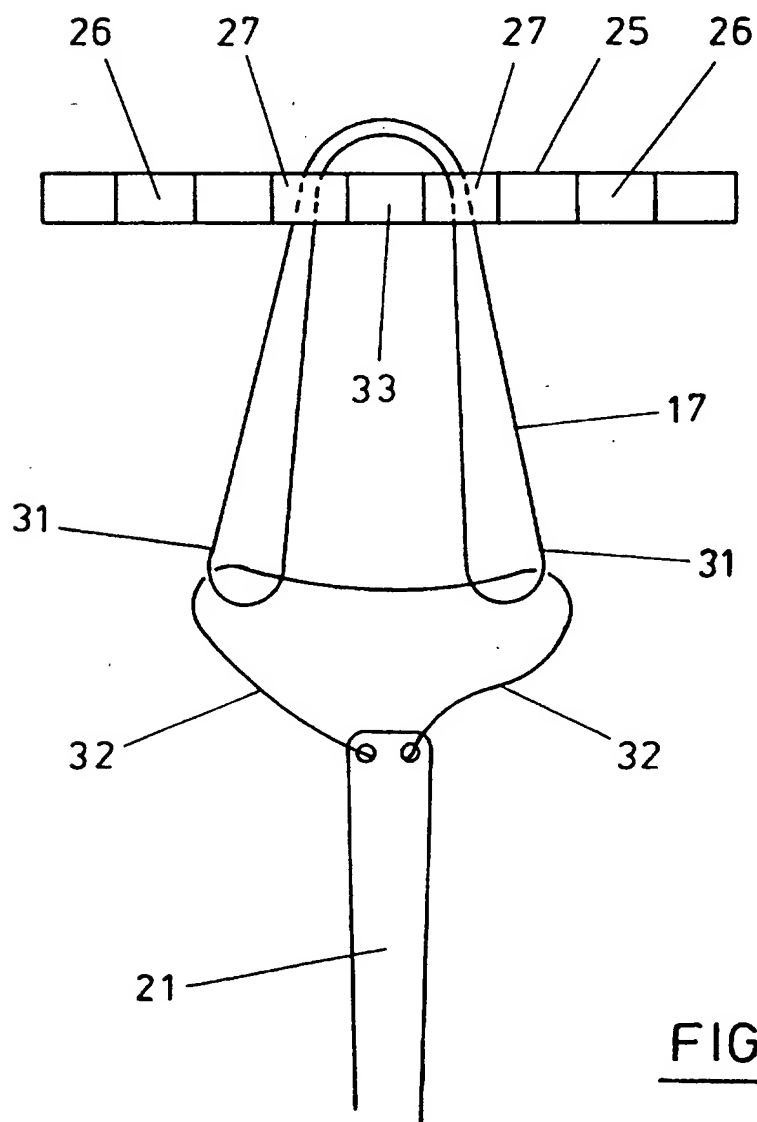
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FIG. 3FIG. 6

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FIG. 4FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/02613

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/08 A61B17/06 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 306 301 A (GRAF BEN K ET AL) 26 April 1994 see abstract; figures see column 4, line 67 - column 5, line 17 see column 5, line 43 - line 58 ---	1,5
A	DE 296 07 352 U (AESCULAP WERKE AG) 1 August 1996 see figures ---	1,5
A	EP 0 170 358 A (SHOWELL A W SUGICRAFT LTD) 5 February 1986 see abstract; figures ---	1-4
A	DE 42 07 854 A (KLEMM BERND) 16 September 1993 -----	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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